Standard Operating Procedure (SOP)

Archiving of Clinical Trials and Research Studies Conducted at St George's

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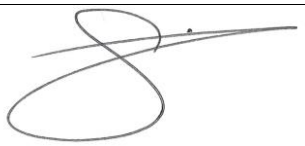
Signature of Authoriser:			

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SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1.0	Original Version	Ira Jakupovic
V2.0	Review of Original Version	Ira Jakupovic
V3.0	Renumbering and reformat in new SOP template. Instruction for preparation of files and associated documentation in relation to All Clinical trials conducted at St George's for archiving aimed at Investigators	Debs Rolfe
V4.0	Named Archivist added. Role of CRGM manager in decision following failed attempts for Sponsor contact. Details added with regards to retention periods. Addition of checklists for Investigators where SG Sponsor. Sponsor files must be archived separately from site files, clearly defining responsibilities of Archivist and clinical team	Debs Rolfe
V5.0	Minimum retention period updated in line with SGUL library policy. Archivist JRES delegate added. Addition of Summary Close out Report	Debs Rolfe`
V6.0	Administrative update to change in name of Joint Research and Enterprise Service and SOP nomenclature. Update of position of named archivist and process. Updated process for archiving.	Georgia Bullock

Associated JRES documents

SOPs	WPDs	Docs	LOGs
	JRESWPD0011 Archiving JRESWPD0023 General Research Definitions		

Contents

1. Background

It is a legal requirement that essential documents and the medical records of trial participants are retained following the end of a CTIMP (Clinical Trial of an Investigational Medicinal Product) in order to allow the reconstruction of a trial, potential further analysis of the data and to enable MHRA inspection and monitoring in accordance with the legislation and with Good Clinical Practice.

Archiving of research records requires systematic storing of a large volume of trial-related documentation at a safe and protected repository which meets professional archiving standards and adheres to current Data Protection legislation. 'Iron Mountain Incorporated' is the current St George's clinical research archiving service provider.

The regulations and standards for the archiving of CTIMPs will also be applied to the archiving of trial-related documentation for non-CTIMPs conducted at St George's. This will include all clinical research, falling under the current UK Policy Framework for Health and Social Care which is conducted at St George's.

The recommended minimum period of retention for studies, from the End of Trial, is outlined in Appendix 1. This can be extended on a study basis depending on the funding and/or sponsor requirements and rationale should be provided.

2. Joint Research and Enterprise Service (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and University policies and procedures.

The JRES acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHFT). St George's will be the official name used on all SOPs to represent both institutions acting as Sponsor.

3. Scope

The purpose of this SOP is to describe the procedure for archiving the project documentation for St George's hosted and sponsored CTIMPs and to describe the procedure for archiving hosted and sponsored non-CTIMP research.

The JRES Working Practice Document JRESWPD0011 should be used in conjunction with this SOP, as this details the procedures for the transfer of archived studies to the service provider and the role of the SGHFT Health Records department.

4. Definitions

For general research-related acronyms used in this SOP, refer to the General Research Definitions Working Practice Document (JRESWPD0023).

4.1 Trial Master File (TMF)

The TMF is a file which contains all the documents that demonstrates that the trial has been conducted in accordance with regulatory requirements and ICH GCP. The TMF is set up at the start of a study and is archived at the end of the study for a set period of time which should be defined in the protocol, the Clinical Trials Agreement or the Delegation of Duties or Sponsorship Agreement. The TMF may take the form of different media e.g. paper or / and electronic. The TMF will contain essential documents which enable both the conduct and quality of the trial to be evaluated.

4.2 Investigator Site File (ISF)

The ISF is provided to the site (along with a Pharmacy Site File, if applicable) at the Site Initiation Visit. It contains all the information site staff will need to carry out the clinical trial at the site. The ISF forms part of the TMF and is archived at the end of the study; however, unless otherwise agreed with the Sponsor, the Investigator is responsible for archiving the ISF in a different location to the TMF. For studies that are Sponsored by St George's the TMF and ISF should be clearly identifiable and will be archived separately with the exception of single centre studies where the TMF and ISF are generated as one file.

4.3 Named Research Archivist

The Research Development and Governance Manager (RDGM) within the JRES is the named Research Archivist for St George's. Certain tasks within this SOP may be delegated by the Research Archivist to other members of the JRES Governance team and to study team members, where appropriate, but responsibility for these tasks will remain with the Research Archivist.

5. Responsibilities

5.1 Sponsor

The Sponsor has overall responsibility for ensuring that the TMF (including the ISF) are archived appropriately. The task of ensuring that the ISF documents are prepared for archiving and placed into a storage facility (as applicable) is delegated to the host site, as set out in the Site Agreement/ protocol.

The Sponsor, or the CI/trials unit if delegated by the Sponsor, is responsible for notifying sites of the study-specific retention period. For St George's sponsored studies, see Appendix 1. Until such notice is received, measures should be taken by the PI to prevent accidental loss or destruction of the ISF.

5.2 Chief Investigator (CI)/Principal Investigator (PI)

The CI and PI are responsible for ensuring the study files are prepared for archiving - this applies in the case of either trials sponsored by St George's and to those studies (or trials) that are sponsored by a third party and that are hosted by St George's.

For multi-centre trials that are sponsored by St George's, the PI at the respective sites will be responsible for the preparation and the subsequent archiving of the ISF in accordance with the requirements agreed between St George's and the host institution.

The archiving arrangements and any specified requirements should be detailed within the protocol and/or any site agreements between the Sponsor and host site(s).

5.3 The Named Research Archivist

The Research Archivist is responsible for ensuring that any team member that is delegated tasks covered by this SOP are appropriately trained to undertake the specific role assigned to them.

The Archivist is responsible for ensuring that the EDGE system is kept up-to-date with the archiving information, controlling access of material in and out of external storage and requesting the destruction of archived material for St George's sponsored and hosted studies. The archivist is not responsible for the content of the archived material.

6. Procedure

a) Archiving of study documentation should occur as soon as possible after study completion, when any queries from the Close-Out visit have been actioned and the data is deemed to be complete and accurate. For studies not sponsored by St George's, notification from the Sponsor should be received to confirm that archiving can take place. The final report for the study should be stored electronically by the JRES and CI if archiving occurs prior to the report being available.

b) The Investigator must confirm with the Research Archivist or their designee that the study will require archiving and must obtain sufficient archiving boxes from the Research Archivist or their delegate.

c) The Investigator must contact any support departments holding documentation that would be required to reconstruct the study (eg: pharmacy, labs etc), requesting that documentation be provided to them for incorporation into the study archive. They may be required to sign a transfer/receipt document. Where copies of the same document are held more than once, only one document should be retained and where possible this should be the signed original.

d) The Investigator must prepare all documents for archiving as follows:

   i. Remove the paperwork from level arch files, securing with treasury tags where appropriate to ensure each section is retained in order.

   ii. Remove documents from plastic wallets, again securing with treasury tags where appropriate.

   iii. Remove staples/paperclips, securing with treasury tags where appropriate.

   iv. Remove '*post it*' notes from documents. Where the notes provide details required to reconstruct the trial, these should be written onto the document concerned, or explained in a file note included in that section of the file.

   v. Identify any documents that are 'carbon copies' or 'NCI paper', photocopy these and ensure that these are filed in the appropriate place.

vi. *Electronic files* – guidance may be sought from the Sponsor but where St. George's is the Sponsor organisation, there are 3 options for the retention of Electronic files:

1) A restricted access shared drive where electronic files are moved into an area specifically marked as 'ARCHIVE' which is password-protected. Details of the location and password must be provided to the Research Archivist.
2) Electronic data is transferred onto suitable media storage hardware, eg: a Compact Disc/USB which is clearly labelled with the study reference codes and contents. Documents must be saved in a format which allows it to be viewed if needed and must also be placed at the top of the archive boxes.
3) The electronic files are all printed off and listed in the contents listings and archived with the rest of the ISF/TMF. Any encription passwords for USBs/CD/e-files should be clearly outlined within the ISF/TMF.

e) The Investigator must transfer the documentation to the archiving boxes taking the following into consideration:

i. Archiving boxes should, where possible, contain complete sections of the documentation.
ii. Archiving boxes should contain as many documents as required to fill a box, to prevent documents from being damaged by movement during transit, and to reduce the costs of archiving. (ie: multiple part-filled boxes are not acceptable).
iii. Archiving boxes must not be filled beyond the fill line displayed on the box.
iv. It is advisable for Investigators to maintain records of the contents of each box.
v. Individual archiving boxes should not contain documentation for more than one study.

f) Once each box is full, the Investigator must ensure that the following information is available for the completion of the Iron Mountain documentation:

i. Project Title/Acronym
ii. PI Name
iii. Nominated contact for the study
iv. JRES Reference Number
v. Box contents (e.g. TMF section 1 & 2, Pharmacy File, etc)
vi. Proposed date of destruction

g) The archive boxes must be kept within the relevant department until collection is arranged. Boxes are not to be moved around the site to avoid loss and/or damage.

h) Once the Investigator has confirmed that all study documentation is secured in the archive boxes, the Research Archivist or delegated individual will need to ensure that the Iron Mountain paperwork is completed and the boxes labelled. The Research Archivist or delegated individual will then arrange for St George's Health Records department to collect the boxes and they will then arrange a collection by Iron Mountain. **The process for this is described in JRESWPD0011.**

i) Boxes may need to be retrieved from the archive at a later date. All requests for retrieval must be received by the Research Archivist or their delegate from the Investigator or their appropriate delegate. **The process for the retrieval and return of archived studies is described in JRESWPD0011.**

Destruction of Archived Records

a) All efforts must be made to receive permission from the Sponsor that destruction of a particular study can take place.

b) In the event that the Sponsor cannot be contacted following 3 documented failed attempts, within a three month period, the Head of Research Governance and Delivery must be consulted to confirm destruction can take place.

c) Prior to destruction authorisation, consideration must be given as to whether any documents may be required for any ongoing legal proceedings. This can be confirmed in **writing** by the Research Development and Governance Manager or via the Head of Research Governance and Delivery.

d) A request for destruction must be communicated via the Health Records off-site team in writing. Copies of requests must be retained by the JRES.

e) The Research Archivist or delegated individual will retain the Certificate of Destruction along with documented communication regarding b,c, and d above, on the study electronic file and also will upload them to the study-specific EDGE entry in the file's Archiving section.

7. References

ICH GCP

European Document Retention Guide – Iron Mountain.

8. Appendices

Appendix 1: Minimum suggested retention periods

Appendix 1

Retention Periods

Type of Study	Retention Period	When should files be destroyed
SGUL/SGHT sponsored CTIMP	15 years (unless longer period suggested by funder) and/or for at least two years after the granting of the last marketing authorisation in the European Community	15 years following EOT declaration
Non-commercial externally sponsored CTIMP	10 years (unless longer period suggested by Sponsor)	Sponsor will confirm when destruction can occur
Commercial externally sponsored CTIMP	10 years (unless longer period suggested by Sponsor)	Sponsor will confirm when destruction can occur
SGUL/SGHT sponsored regulated device investigation	15 years	15 years following EOT declaration
Externally Sponsored regulated device Investigation	10 years (unless longer period suggested by Sponsor)	Sponsor will confirm when destruction can occur
Non-interventional study (SGUL/SGHT and externally sponsored)	5 years (unless longer period suggested by Sponsor and/or funder)	Sponsor will confirm when destruction can occur (externally) and/or 5 years following EOT declaration
Interventional study (non-CTIMP/Device SGUL/SGHT and externally sponsored)	5 years (unless longer period suggested by Sponsor and/or funder)	Sponsor will confirm when destruction can occur (externally) and/or 5 years following EOT declaration
ATMP studies Sponsored by SGHT/SGUL or externally sponsored	30 years following expiration of product	Sponsor will confirm when destruction can occur